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510(k) Summary of Safety and Effectiveness
UroMed® CaverMap Surgical Aid Fine Probe Tip
Tuesday, January 09, 2001

Company Name

UroMed® Corporation
1400 Providence Highway
Norwood, MA 02062

Official Contact

Frederick Tobia
Director, Regulatory, Quality and Clinical Affairs

Device Name

Proprietary Name:	UroMed CaverMap® Surgical Aid
Common Name:	Nerve Stimulator/Locator
Classification Name(s):	21 CFR § 874.1820 Stimulator, Nerve 21 CFR § 876.4730 Probe And Director, Gastro-Urology

Predicate Devices used for Substantial Equivalence

UroMed CaverMap Surgical Aid	K970971, K993436, K000507

Intended Use

The UroMed CaverMap Surgical Aid is intended to provide stimulation to the body to locate and identify nerves and to test their excitability.

Indications for Use

The UroMed CaverMap® Surgical Aid Fine Probe Tip II is an accessory in the UroMed CaverMap® Surgical Aid System. The system is indicated for use in the stimulation of the cavernosal and associated parasympathetic nerves during open prostatectomy and colorectal (surgical) procedures in males. The device aids the surgeon in locating these nerves. The device is designed as an adjunct to the current open Prostatectomy and Colorectal procedures in which a nerve sparing technique is used. The Surgical Aid is not designed to replace the surgeon's expertise in mapping out the neurovascular bundles. Each surgeon's skill determines whether these nerves are spared regardless of any aid.

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Description

The UroMed CaverMap Surgical Aid Fine Probe Tip II is the disposable electrode-containing tip for use with the CaverMap Surgical Aid System. The probe tip houses the electrodes that are placed over nerves during stimulation. The Fine Probe Tip incorporates a two-electrode design, with directly visible electrodes. The currently marketed fine probe tip houses two electrodes that are not directly visible, with markings indicating the location of the electrodes. The Fine Probe Tip II was designed based on Physician preference to have an electrode array that was directly visible allowing for exact identification of the electrode placement.

Summary of Standards Achieved

FDA Quality Systems Regulation 21 CFR § 820
ISO 46001: Quality System
ISO 10993-1: Biological Evaluation of Medical Devices
IEC 601

Summary

In summary, the UroMed CaverMap Surgical Aid Fine Probe Tip II is substantially equivalent to legally marketed devices. Quality System Controls assure the device is substantially equivalent to the predicate devices with respect to its performance, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Frederick Tobia
Director, Regulatory, Quality & Clinical Affairs
UroMed Corporation
1400 Providence Highway
Building 2
NORWOOD MA 02062

Re: K010098
Modification to Cavermap Surgical Aid
Dated: January 10, 2001
Received: January 11, 2001
Regulatory Class: II
21 CFR §876.4730/Procode: 78 FGM

Dear Mr. Tobia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K010098

Device Name: UroMed CaverMap® Surgical Aid

Indications for Use: The UroMed CaverMap® Surgical Aid Fine Probe Tip II is an accessory in the UroMed CaverMap® Surgical Aid System. The system is indicated for use in the stimulation of the cavernosal and associated parasympathetic nerves during open prostatectomy and colorectal (surgical) procedures in males. The device aids the surgeon in locating these nerves. The device is designed as an adjunct to the current open Prostatectomy and Colorectal procedures in which a nerve sparing technique is used. The Surgical Aid is not designed to replace the surgeon's expertise in mapping out the neurovascular bundles. Each surgeon's skill determines whether these nerves are spared regardless of any aid.

David C. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010098

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)